CDER Drug and Biologic Accelerated and Restricted Distribution Approvals
As of June 30, 2014

This report will be updated January and July of every year

NDA and BLA Accelerated Approvals

NDA/BLA Number	Product Name	FDA Received Date	Accelerated Approval Date	Total Time to Accelerated Approval (Months)	Approval Basis	Accelerated Approval Indication
NDA 205755	ZYKADIA	12/24/2013	4/29/2014	4.1	S	TREATMENT OF PATIENTS WITH ANAPLASTIC LYMPHOMA KINASE (ALK)-POSITIVE METASTATIC NON-SMALL CELL LUNG CANCER (NSCLC) WHO HAVE PROGRESSED ON OR ARE INTOLERANT TO CRIZOTINIB
NDA 203202	NORTHERA	8/14/2013	2/18/2014	6.2	S	TREATMENT OF ORTHOSTATIC DIZZINESS, LIGHTHEADEDNESS, OR THE “FEELING THAT YOU ARE ABOUT TO BLACK OUT” IN ADULT PATIENTS WITH SYMPTOMATIC NEUROGENIC ORTHOSTATIC HYPOTENSION CAUSED BY PRIMARY AUTONOMIC FAILURE (PARKINSON'S DISEASE, MULTIPLE SYSTEM ATROPHY,AND PURE AUTONOMIC FAILURE), DOPAMINE BETA-HYDROXYLASE DEFICIENCY, AND NON-DIABETIC AUTONOMIC NEUROPATHY
NDA 205552	IMBRUVICA	6/28/2013	11/13/2013	4.5	S	TREATMENT OF PATIENTS WITH MANTLE CELL LYMPHOMA (MCL)
NDA 204026	POMALYST (POMALIDOMIDE)	4/10/2012	2/8/2013	10.0	S	TREATMENT OF PATIENTS WITH MULTIPLE MYELOMA WHO HAVE RECEIVED AT LEAST TWO PRIOR THERAPIES INCLUDING LENALIDOMIDE AND BORTEZOMIB AND HAVE DEMONSTRATED DISEASE PROGRESSION ON OR WITHIN 60 DAYS OF COMPLETION OF THE LAST THERAPY
NDA 204384	SIRTURO (BEDAQUILINE)	6/29/2012	12/28/2012	6.0	S	COMBINATION THERAPY IN ADULTS (≥ 18 YEARS) WITH PULMONARY MULTI-DRUG RESISTANT TUBERCULOSIS (MDR-TB)
NDA 203469	ICLUSIG (PONATINIB)	9/27/2012	12/14/2012	2.6	S	TREATMENT OF ADULT PATIENTS WITH CHRONIC PHASE, ACCELERATED PHASE, OR BLAST PHASE CHRONIC MYELOID LEUKEMIA (CML) THAT IS RESISTANT OR INTOLERANT TO PRIOR TYROSINE KINASE INHIBITOR THERAPY OR PHILADELPHIA CHROMOSOME POSITIVE ACUTE LYMPHOBLASTIC LEUKEMIA (PH+ALL) THAT IS RESISTANT OR INTOLERANT TO PRIOR TYROSINE KINASE INHIBITOR THERAPY
NDA 203585	SYNRIBO (OMACETAXINE MEPESUCCINATE)	3/30/2012	10/26/2012	6.9	S	TREATMENT OF ADULT PATIENTS WITH CHRONIC OR ACCELERATED PHASE CHRONIC MYELOID LEUKEMIA (CML) WITH RESISTANCE AND/OR INTOLERANCE TO TWO OR MORE TYROSINE KINASE INHIBITORS (TKI)

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NDA 203985	AFINITOR DISPERZ (EVEROLIMUS TABLETS FOR ORAL SUSPENSION)	2/29/2012	8/29/2012	6.0	S	TREATMENT OF PEDIATRIC AND ADULT PATIENTS WITH TUBEROUS SCLEROSIS COMPLEX (TSC) FOR THE TREATMENT OF SUBEPENDYMAL GIANT CELL ASTROCYTOMA (SEGA) THAT REQUIRES THERAPEUTIC INTERVENTION BUT CANNOT BE CURATIVELY RESECTED
NDA 202497	MARQIBO (VINCRISTINE SULFATE LIPOSOME INJECTION)	7/12/2011	8/9/2012	13.0	S	TREATMENT OF ADULTS WITH PHILADELPHIA (PH) CHROMOSOME NEGATIVE (-) ACUTE LYMPHOBLASTIC LEUKEMIA (ALL) IN SECOND RELAPSE OR WHOSE DISEASE HAS PROGRESSED FOLLOWING TWO OR GREATHER TREATMENT LINES OF ANTI-LEUKEMIA THERAPIES
NDA 202714	KYPROLIS (CARFILZOMIB)	9/27/2011	7/20/2012	9.8	S	TREATMENT OF PATIENTS WITH MULTIPLE MYELOMA WHO HAVE RECEIVED AT LEAST TWO PRIOR THERAPIES INCLUDING BORTEZOMIB AND AN IMMUNOMODULATORY AGENT AND HAVE DEMONSTRATED DISEASE PROGRESSION ON OR WITHIN 60 DAYS OF COMPLETION OF THE LAST THERAPY
NDA 021825	FERRIPROX (DEFERIPRONE)	1/30/2009	10/14/2011	32.4	S	TREATMENT OF CHRONIC IRON OVERLOAD IN PATIENTS WITH TRANSFUSION -DEPENDENT ANEMIAS
NDA 202570	XALKORI	3/30/2011	8/26/2011	4.9	S	TREATMENT OF PATIENTS WITH LOCALLY ADVANCED OR METASTATIC NON-SMALL CELL LUNG CANCER (NSCLC) THAT IS ANAPLASTIC LYMPHOMA KINASE (ALK)-POSITIVE AS DETECTED BY AN FDA APPROVED TEST
BLA 125388	BRENTUXIMAB VEDOTIN	2/28/2011	8/19/2011	5.7	S	TREATMENT OF PATIENTS WITH HODGKIN LYMPHOMA AFTER FAILURE OF AUTOLOGOUS STEM CELL TRANSPLANT (ASCT) OR AFTER FAILURE OF AT LEAST TWO PRIOR MULTI-AGENT CHEMOTHERAPY REGIMENS IN PATIENTS WHO ARE NOT ASCT CANDIDATES
NDA 021945	MAKENA (HYDROXYPROGESTERONE CAPROATE)	4/20/2006	2/3/2011	57.5	S	TO REDUCE THE RISK OF PRETERM BIRTH IN WOMEN WITH A SINGLETON PREGNANCY WHO HAVE A HISTORY OF SINGLETON SPONTANEOUS PRETERM BIRTH.
BLA 125326	OFATUMUMAB	1/30/2009	10/26/2009	8.8	S	TREATMENT OF PATIENTS WITH CHRONIC LYMPHOCYTIC LEUKEMIA (CLL) REFRACTORY TO FLUDARABINE AND ALEMTUZUMAB
NDA 022468	FOLOTYN	3/24/2009	9/24/2009	6.0	S	RELAPSED OR REFRACTORY PERIPERAL T-CELL LYMPHOMA
NDA 022273	FLUDARABINE PHOSPHATE TABS FOR ORAL USE	11/19/2007	12/18/2008	13.0	S	TREATMENT OF ADULTS PTS WITH B CELL CHRONIC LYMPHOCYTIC LEUEMIA (CLL) WHO HAVE NOT RESPONDED TO WHOSE DISEASE HAS PROGRESSED DURING OR AFTER TREATMENT WITH AT
NDA 022291	PROMACTA	12/19/2007	11/20/2008	11.1	S	SHORT TERM IDIOPATHIC THROMBOCYTOPAENIC PUPURA (ITP)
NDA 022187	TMC 125 ETRAVIRINE	7/18/2007	1/18/2008	6.0	S	TREATMENT OF HIV
NDA 022068	TASIGNA (NILOTINIB, AMN107)	9/29/2006	10/29/2007	13.0	S	TREATMENT OF GLEEVEC RESISTANT OR INTOLERANT ADULT PTS WITH PHILADELPHIA CHROMOSONE POSITIVE CHRONIC MYELOGENOUS LEUKEMIA IN CHRONIC PHASE & ACCELERATED PHASE

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NDA 022145	ISENTRESS	4/13/2007	10/12/2007	6.0	S	IN COMBINATION WITH OTHER ANTIRETROVIRAL AGENTS FOR THE TREATMENT OF HIV 1 INFECTION
NDA 022128	SELZENTRY, MARAVIROC, UK-427,857	12/20/2006	8/6/2007	7.5	S	TREATMENT OF PATIENTS WITH CCR5-TROPIC HIV-1
BLA 125147	PANITUMUMAB	3/29/2006	9/27/2006	6.0	S	TREATMENT OF EGFR-EXPRESSING, METASTATIC COLORECTAL CARCINOMA WITH DISEASE PROGRESSION ON OR FOLLOWING FLUOROPYRIMIDINE-, OXALIPLATIN-, AND IRINOTECAN-CONTAINING CHEMOTHERAPY REGIMENS
NDA 021986	SPRYCEL	12/28/2005	6/28/2006	6.0	S	FOR CHRONIC MYELOGENOUS LEUKEMIA
NDA 021976	PREZISTA	12/23/2005	6/23/2006	6.0	S	TREATMENT OF HIV INFECTION
NDA 021882	EXJADE (DEFERASIRIX)	5/2/2005	11/2/2005	6.0	S	TREATMENT OF CHRONIC IRON OVERLOAD DUE TO BLOOD TRANSFUSIONS IN ADULT AND PEDIATRIC PATIENTS AS YOUNG AS TWO YEARS OF AGE
NDA 021877	ARRANON (NELARABINE)	4/29/2005	10/28/2005	6.0	S	TREATMENT OF PEDIATRIC AND ADULT PATIENTS WITH T-CELL ACUTE LYMPHOBLASTIC LEUKEMIA OR T-CELL LYMPHOBLASTIC LYMPHOMA
NDA 021814	APTIVUS (TIPRANAVIR) 250MG CAPSULES	12/22/2004	6/22/2005	6.0	S	TREATMENT OF HIV-1 INFECTION
NDA 021673	CLOFARABINE	3/30/2004	12/28/2004	9.0	S	TREATMENT OF ACUTE LYMPHOCYTIC LEUKEMIA
BLA 125104	NATALIZUMAB	5/24/2004	11/23/2004	6.0	S	TREATMENT OF PATIENTS WITH RELAPSING FORMS OF MULTIPLE SCLEROSIS (MS) TO REDUCE THE FREQUENCY OF CLINICAL EXACERBATIONS
NDA 021322	LUVERIS (LUTROPIN ALPHA) INJ 75IU	5/1/2001	10/8/2004	41.3	S	LUVERIS ADMINISTERED WITH FOLLITROPIN ALFA FOR INJECTION IS INDICATED FOR STIMULATION OF FOLLICULAR DEVELOPMENT IN WOMEN WITH SEVERE DEFICIENCY IN LH AND FSH
NDA 021752	EMTRICITABINE 200MG/TENOFOVIR DISOPROXIL	3/12/2004	8/2/2004	4.7	S	TREATMENT OF HIV INFECTION
BLA 125084	CETUXIMAB	8/14/2003	2/12/2004	6.0	S	TREATMENT OF EGFR-EXPRESSING, METASTATIC COLORECTAL CARCINOMA IN PATIENTS WHO ARE REFRACTORY TO IRINOTECAN-BASED CHEMOTHERAPY (IN COMBINATION WITH IRINOTECAN); TREATMENT OF EGFR-EXPRESSING, METASTATIC COLORECTAL CARCINOMA IN PATIENTS WHO ARE INTOLER
NDA 021602	VELCADE (BORTEZOMIB) INJ 3.5MG	1/21/2003	5/13/2003	3.7	S	TREATMENT OF RELAPSED/REFRACTORY MULTIPLE MYELOMA
NDA 021399	IRESSA (GEFITINIB) TABLETS	8/5/2002	5/5/2003	9.0	S	TREATMENT OF NON-SMALL CELL LUNG CANCER
BLA 103979	AGALSIDASE BETA	6/23/2000	4/24/2003	34.0	S	USE IN PATIENTS WITH FABRY DISEASE TO REDUCE GLOBOTRIAOSYLCERAMIDE (GL-3) DEPOSITION IN CAPILLARY ENDOTHELIUM OF THE KIDNEY AND CERTAIN OTHER CELL TYPES

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NDA 021588	GLEEVEC (IMATINIB MESYLATE) 100/400MG	12/16/2002	4/18/2003	4.0	S	TREATMENT OF PHILADELPHIA POSITIVE CHRONIC MYELOID LEUKEMIA
NDA 021481	FUZEON	9/16/2002	3/13/2003	5.9	S	TREATMENT OF HIV1/AIDS
NDA 021492	ELOXATIN(OXALIPLATIN)INJECTION 50MG/100M	6/24/2002	8/9/2002	1.5	S	TREATMENT FOR COLORECTAL CANCER
NDA 021272	REMODULIN(TREPROSTINIL SODIUM)1/2.5/10	10/16/2000	5/21/2002	19.1	S	TREATMENT FOR PULMONARY ARTERIAL HYPERTENSION
BLA 125019	IBRITUMOMAB TIUXETAN	11/1/2000	2/19/2002	15.6	S	TREATMENT OF PATIENTS WITH RELAPSED OR REFRACTORY LOW-GRADE, FOLLICULAR, OR TRANSFORMED B-CELL NON-HODGKIN'S LYMPHOMA: (NOT ACC. APP.) INCLUDING PATIENTS WITH RITUXIMAB (RITUXAN) REFRACTORY FOLLICULAR NON-HODGKIN'S LYMPHOMA
NDA 021356	VIREAD(TENOFOVIR DISOPROXIL FUMARATE)300	5/1/2001	10/26/2001	5.9	S	TREATMENT OF HIV-1 INFECTION IN ADULTS
NDA 021335	GLEEVEC (IMATINIB MESYLATE) 50/100 MG	2/27/2001	5/10/2001	2.4	S	TREATMENT OF CHRONIC MYELOID LEUKEMIA
BLA 103948	ALEMTUZUMAB	12/23/1999	5/7/2001	16.5	S	TREATMENT OF B-CELL CHRONIC LYMPHOCYTIC LEUKEMIA (B-CLL) IN PATIENTS WHO HAVE BEEN TREATED WITH ALKYLATING AGENTS AND WHO HAVE FAILED FLUDARABINE THERAPY
NDA 021205	TRIZIVIR	12/17/1999	11/14/2000	10.9	S	TREATMENT OF HIV INFECTION
NDA 021226	KALETRA	6/1/2000	9/15/2000	3.5	S	TREATMENT OF HIV INFECTION
NDA 021251	KALETRA	6/1/2000	9/15/2000	3.5	S	TREATMENT OF HIV
NDA 021174	MYLOTARG	10/29/1999	5/17/2000	6.6	S	TREATMENT OF RELAPSED ACUTE MYELOID LEUKEMIA
NDA 050747	SYNERCID(DALFOPRISTIN/QUINUPRISTIN)IV 50	9/5/1997	9/21/1999	7.8†	S	INFECTIONS DUE TO VREF INCLUDING CASES ASSOCIATED WITH CONCURRENT BACTEREMIA AND INFECTIONS CAUSED BY STAPHYLOCOCCUS AUREAS/INCLUDING METHICILLIN SUSCEPTIBLE AN
NDA 021029	TEMODAR (TEMOZOLOMIDE)	8/13/1998	8/11/1999	11.9	S	TREATMENT OF RECURRENT GLIOMA/ADVANCED METASTATIC MELANOMA
NDA 021007	AGENERASE	10/16/1998	4/15/1999	6.0	S	TREATMENT OF HIV-1 INFECTION
NDA 021039	AGENERASE	12/8/1998	4/15/1999	4.2	S	TREATMENT OF HIV INFECTION
NDA 021041	DEPOCYT	10/5/1998	4/1/1999	5.9	S	INTRATHECAL TREATMENT OF LYMPHOMATOUS MENINGITIS
BLA 103767	DENILEUKIN DIFTITOX	12/9/1997	2/5/1999	13.9	S	TREATMENT OF PERSISTENT OR RECURRENT CUTANEOUS T-CELL LYMPHOMA (ORPHAN INDICATION)
NDA 020977	ZIAGEN	6/24/1998	12/17/1998	5.8	S	TREATMENT OF HIV INFECTION
NDA 020978	ZIAGEN	6/24/1998	12/17/1998	5.8	S	TREATMENT OF HIV INFECTIONS
NDA 020972	SUSTIVA	6/11/1998	9/17/1998	3.2	S	TREATMENT OF HIV
NDA 020933	VIRAMUNE (NEVIRAPINE) SUSPENSION	4/20/1998	9/11/1998	4.7	S	FOR USE IN COMBINATION WITH OTHER ANTIRETROVIRAL AGENTS FOR TREATMENT OF HIV-1 INFECTION

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BLA 103772	INFLIXIMAB	12/30/1997	8/24/1998	7.8	S	TREATMENT OF MODERATELY TO SEVERELY ACTIVE CROHN'S DISEASE FOR THE REDUCTION OF THE SIGNS AND SYMPTOMS, IN PATIENTS WHO HAVE AN INADEQUATE RESPONSE TO CONVENTIONAL THERAPIES AND TREATMENT OF PATIENTS WITH FISTULIZING CROHN'S DISEASE FOR THE REDUCTIO
NDA 021024	PRIFTIN (RIFAPENTINE) 150 MGS TABLETS	12/22/1997	6/22/1998	6.0	S	TREATMENT OF PULMONARY TUBERCULOSIS
NDA 019832	SULFAMYLON	3/31/1997	6/5/1998	14.2†	S	ADJUNCTIVE THERAPY IN PATIENTS WITH SECOND AND THIRD-DEGREE BURNS
NDA 020896	XELODA	10/31/1997	4/30/1998	6.0	S	TREATMENT OF METASTATIC BREAST CANCER
NDA 020705	RESCRIPTOR	7/15/1996	4/4/1997	8.6	S	TREATMENT OF HIV-1 INFECTION
NDA 020778	VIRACEPT (NELFINAVIR MESYLATE) PEDIATRIC	12/26/1996	3/14/1997	2.6	S	TREATMENT OF HIV INFECTION IN CHILDREN WHEN ANTIRETROVIRAL THERAPY IS INDICATED
NDA 020779	VIRACEPT (NELFINAVIR MESYLATE) 250MG TAB	12/26/1996	3/14/1997	2.6	S	TREATMENT OF HIV INFECTION WHEN ANTIRETROVIRAL THERAPY IS WARRANTED
NDA 019815	PROAMATINE	9/25/1995	9/6/1996	11.4†	S	IDIOPATHIC ORTHOSTATIC HYPROTENSION
NDA 020604	SEROSTIM (SOMATROPIN) FOR INJECTION 6MG	9/11/1995	8/23/1996	11.4	S	TREATMENT OF AIDS WASTING AND CACHEXIA
NDA 020636	VIRAMUNE (NEVIRAPINE) ORAL TABS 200MG	2/23/1996	6/21/1996	3.9	S	COMBINATION OF VIRAMUNE WITH NUCLEOSIDE ANTIRETROVIRAL AGENTS IN PREVIOUSLY TREATED PATIENTS FOR WHOM CURRENT THERAPY IS DEEMED INADEQUATE
NDA 020571	CAMPTOSAR (IRINOTECAN HCL TRIHYDROTE) IV	12/28/1995	6/14/1996	5.6	S	FOR REFRACTORY COLO RECTAL CANCER
NDA 020449	TAXOTERE	7/27/1994	5/14/1996	21.6	S	PATIENTS WITH LOCALLY ADVANCED OR METASTATIC BREAST CARCINOMA IN WHOM PREVIOUSTHERAPY HAS FAILED / PATIENTS WITH LOCALLY ADVANCED OR METASTATIC NON SMALL CELL
NDA 020685	CRIXIVAN	1/31/1996	3/13/1996	1.4	S	TREATMENT OF ADULTS WITH HIV-1 INFECTIONS
NDA 020680	NORVIR (RITONAVIR)	12/21/1995	3/1/1996	2.3	S	TREATMENT OF HIV INFECTION
NDA 020659	NORVIR (RITONAVIR) ORAL SOLUTION	12/21/1995	3/1/1996	2.3	S	TO TREAT HIV INFECTION
NDA 020628	INVIRASE(SAQUINAVIR MESYLATE) 200MG CAPS	8/31/1995	12/6/1995	3.2	S	MONOTHERAPY AND COMBINATION TREATMENT (WITH HIVID AND/OR ZDV) FOR PATIENTS WITHADVANCED HIV INFECTION
NDA 020596	EPIVIR	7/7/1995	11/17/1995	4.4	S	TREATMENT OF HIV INFECTION IN SELECTED PATIENTS
NDA 050718	DOXIL	9/7/1994	11/17/1995	14.3	S	TREATMENT OF KAPOSI'S SARCOMA IN AIDS PATIENTS WHO HAVE FAILED PRIOR SYSTEMIC COMBINATION CHEMOTHERAPY EITHER DUE TO PROGRESSION OF DISEASE OR UNACCEPTABLE TOXI
NDA 020564	EPIVIR	7/7/1995	11/17/1995	4.4	S	TREATMENT OF HIV INFECTION IN SELECTED PATIENTS
NDA 020498	CASODEX	9/14/1994	10/4/1995	12.7	S	USE IN COMBINATION THERAPY WITH EITHER AN LHRH ANALOGUE OR SURGICAL CASTRATION FOR THE TREATMENT OF ADVANCED PROSTATE CANCER
NDA 020212	ZINECARD	8/5/1994	5/26/1995	9.7†	S	ZINECARD FOR INJECTION IS INDICATED FOR THE PREVENTION OF CARDIOMYOPATHY ASSOCIATED WITH DOXORUBICIN ADMINISTRATION

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NDA 020412	ZERIT (STAVUDINE) CAPS 5/15/20/30/40MG	12/28/1993	6/24/1994	5.9	S	ADULT PATIENTS WITH HIV INFECTION WHO HAVE RECEIVED ZIDOVUDINE THERAPY AND PEDIATRIC PATIENTS 3 MO TO 12 YRS WITH SYMPTOMATIC HIV INFECTION OR WITH SIGNIFICANT
NDA 050698	BIAXIN	11/2/1992	12/23/1993	13.7	S	ANTIBIOTIC PEDIATRIC SUSPENSION
BLA 103471	INTERFERON BETA-1B	6/18/1992	7/23/1993	13.2	S	TREATMENT OF MULTIPLE SCLEROSIS (ORPHAN DESIGNATION)
NDA 020199	HIVID (ZALCITABINE) TABLETS	10/31/1991	6/19/1992	7.6	S	TREATMENT OF HIV-INFECTED PATIENTS WITH AIDS OR ADVANCED AIDS-RELATED COMPLEX

NDA and BLA Restricted Distribution Approvals

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NDA 022081	LETAIRIS	12/18/2006	6/15/2007	5.9	R	PULMONARY HYPERTENSION
NDA 021880	REVLIMID(LENALIDOMIDE)	4/7/2005	12/27/2005	8.7	R	TREATMENT OF PATIENTS WITH TRANSFUSION-DEPENDENT ANEMIA
NDA 021320	PLENAXIS DEPOT (ABARELIX) DEPOT SUSPENSI	12/12/2000	11/25/2003	35.4	R	TREATMENT FOR PROSTATIC CANCER WHERE ORCHIECTOMY/ESTROGEN ADMINISTRATION/OR AGONIST THERAPY IN EITHER NOT INDICATED/ UNACCEPTABLE TO THE PATIENT
NDA 021196	XYREM (SODIUM OXYBATE) 500MG/ML ORAL SOL	10/2/2000	7/17/2002	21.5	R	TREATMENT TO REDUCE THE INCIDENCE OF CATAPLEXY AND TO IMPROVE THE SYMPTOM OF DAYTIME SLEEPINESS IN PATIENTS WITH NARCOLEPSY
NDA 021290	TRACLEER	11/17/2000	11/20/2001	12.1	R	PULMONARY ARTERIAL HYPERTENSION
NDA 020687	MIFEPREX	3/18/1996	9/28/2000	18.0†	R	INDUCTION OF ABORTION
NDA 020747	ACTIQ (ORAL TRANSMUCOSAL FENTANYL CITRAT	11/13/1996	11/4/1998	23.7	R	MANAGEMENT OF BREAKTHROUGH CANCER PAIN IN PATIENTS WITH MALIGNANCIES WHO ARE ALREADY RECEIVING AND WHO ARE TOLERANT TO OPIOID THERAPY FOR THEIR UNDERLYING PERSISTENT CANCER PAIN
NDA 020785	THALOMID (THALIDOMIDE) 50MG CAPSULES	12/20/1996	7/16/1998	18.8	R	ACUTE TREATMENT OF ERYTHEMA NODOSUM LEPROSUM AS WELL AS FOR THE MAINTENANCE THERAPY FOR PREVENTION AND SUPPRESSION ERYTHEMA NODOSUM LEPOSUM IN HANSEN'S DISEASE

NDA and BLA Supplement Accelerated Approvals

NDA/BLA Supplement Number	Product Name	FDA Received Date	Accelerated Approval Date	Total Time to Accelerated Approval (Months)	Approval Basis
NDA 205552 / 2	IMBRUVICA	6/28/2013	2/12/2014	7.5	S
NDA 202806 / 2	TAFINLAR	7/9/2013	1/9/2014	6.0	S
NDA 204114 / 1	MEKINIST	7/8/2013	1/8/2014	6.0	S

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BLA 125409 / 51	PERJETA	5/1/2013	9/30/2013	5.0	S
BLA 125151 / 184	IDURSULFASE	9/24/2012	6/24/2013	9.0	S
NDA 021882 / 15	EXJADE (DEFERASIROX)	12/23/2011	1/23/2013	13.1	S
NDA 021882 / 16	EXJADE (DEFERASIROX)	9/17/2012	1/23/2013	4.2	S
NDA 022334 / 17	AFINITOR	12/19/2011	4/26/2012	4.2	S
BLA 125388 / 6	BRENTUXIMAB VEDOTIN	2/28/2011	8/19/2011	5.7	S
NDA 022393 / 4	ROMIDEPSIN FOR INFUSION	12/17/2010	6/16/2011	6.0	S
NDA 022334 / 6	AFINITOR	4/30/2010	10/29/2010	6.0	S
NDA 021986 / 8	SPRYCEL	4/28/2010	10/28/2010	6.0	S
NDA 022068 / 5	TASIGNA (NILOTINIB, AMN107)	12/21/2009	6/17/2010	5.9	S
NDA 022059 / 7	TYKERB TABLETS	3/31/2009	1/29/2010	10.0	S
NDA 022187 / 1	TMC 125 ETRAVIRINE	1/30/2009	11/24/2009	9.8	S
BLA 125085 / 169	BEVACIZUMAB	11/3/2008	5/5/2009	6.0	S
NDA 021588 / 25	GLEEVEC (IMATINIB MESYLATE) 100/400MG	6/24/2008	12/19/2008	5.9	S
NDA 021462 / 15	ALIMTA (PEMETREXED DISODIUM) 500MG VIALS	8/28/2007	9/26/2008	13.0	S
NDA 050718 / 33	DOXIL	8/10/2007	6/10/2008	10.0	S
NDA 020634 / 47	LEVAQUIN	7/5/2007	5/5/2008	10.0	S
NDA 020635 / 51	LEVAQUIN	7/5/2007	5/5/2008	10.0	S
NDA 021721 / 15	LEVAQUIN(LEVOFLAXIN ORAL SOLUTION)25MG/M	7/5/2007	5/5/2008	10.0	S
BLA 125085 / 91	BEVACIZUMAB	5/24/2006	2/22/2008	21.0	S
NDA 021588 / 16	GLEEVEC (IMATINIB MESYLATE) 100/400MG	3/28/2006	9/27/2006	6.0	S
NDA 021430 / 1	THALOMID (THALIDOMIDE) 50MG/100MG/200MG	12/23/2003	5/25/2006	29.1	R,S
NDA 020785 / 31	THALOMID (THALIDOMIDE) 50MG CAPSULES	5/24/2005	5/25/2006	12.0	R,S
NDA 021968 / 1	SUTENT (SUNITINIB)	8/11/2005	1/26/2006	5.5	S
NDA 020726 / 12	FEMARA	6/28/2005	12/28/2005	6.0	S
BLA 125011 / 24	TOSITUMOMAB AND IODINE I 131 TOSITUMOMAB	7/3/2004	12/22/2004	5.7	S
NDA 020634 / 35	LEVAQUIN	5/26/2004	11/24/2004	6.0	S
NDA 020635 / 35	LEVAQUIN	5/26/2004	11/24/2004	6.0	S
NDA 021272 / 2	REMODULIN(TREPROSTINIL SODIUM)1/2.5/10	1/30/2004	11/24/2004	9.8	S
NDA 021721 / 3	LEVAQUIN(LEVOFLAXIN ORAL SOLUTION)25MG/M	11/12/2004	11/24/2004	0.4	S
NDA 020726 / 11	FEMARA	4/29/2004	10/29/2004	6.0	S

CDER Drug and Biologic Accelerated and Restricted Distribution Approvals
As of June 30, 2014

NDA 021677 / 1	ALIMTA (PEMETREXED DISODIUM) 500MG VIALS	11/4/2003	8/19/2004	9.5	S
NDA 021462 / 1	ALIMTA (PEMETREXED DISODIUM) 500MG VIALS	8/13/2004	8/19/2004	0.2	S
NDA 021335 / 3	GLEEVEC (IMATINIB MESYLATE) 50/100 MG	6/28/2002	5/20/2003	10.7	S
NDA 021588 / 1	GLEEVEC (IMATINIB MESYLATE) 100/400MG	4/24/2003	5/20/2003	0.9	S
NDA 021335 / 4	GLEEVEC (IMATINIB MESYLATE) 50/100 MG	6/28/2002	12/20/2002	5.8	S
NDA 020541 / 10	ARIMIDEX	3/5/2002	9/5/2002	6.0	S
NDA 021335 / 1	GLEEVEC (IMATINIB MESYLATE) 50/100 MG	10/16/2001	2/1/2002	3.6	S
NDA 019858 / 21	CIPRO IN SODIUM CHLORIDE 0.9% IN PLASTIC	3/2/2000	8/30/2000	6.0	S
NDA 019537 / 38	CIPRO	3/1/2000	8/30/2000	6.0	S
NDA 019847 / 24	CIPRO	3/2/2000	8/30/2000	6.0	S
NDA 019857 / 27	CIPRO IN DEXTROSE 5% IN PLASTIC CONTAINE	3/2/2000	8/30/2000	6.0	S
NDA 020780 / 8	CIPRO	3/2/2000	8/30/2000	6.0	S
NDA 021156 / 1	CELEBREX (CELECOXIB) 200MG CAPSULES	6/25/1999	12/23/1999	6.0	S
NDA 050718 / 6	DOXIL	12/29/1998	6/28/1999	6.0	S
NDA 020636 / 9	VIRAMUNE (NEVIRAPINE) ORAL TABS 200MG	3/16/1998	9/11/1998	5.9	S
NDA 020221 / 2	ETHYOL	2/9/1996	3/15/1996	1.2	S
NDA 050697 / 1	BIAXIN	11/2/1992	12/23/1993	13.7	S

NDA and BLA Supplement Restricted Distribution Approvals

NDA/BLA Supplement Number	Product Name	FDA Received Date	Approval Date	Total Approval Time (Months)	Approval Basis
NDA 021880 / 1	REVLIMID(LENALIDOMIDE)	12/30/2005	6/29/2006	6.0	R
BLA 125104 / 15	NATALIZUMAB	9/27/2005	6/5/2006	8.3	R
NDA 018662 / 56	ACCUTANE	6/27/2005	8/12/2005	1.5	R
NDA 021107 / 5	LOTRONEX	12/7/2001	6/7/2002	6.0	R

The Therapeutic Biologic Products transferred from CBER to CDER effective 1-Oct-2003.

R - Restricted - Approval with restrictions to assure safe use as recorded in 21 CFR 601.42 (Subpart E) or 21 CFR 314.520 (Subpart H).

S - Surrogate - Approval based on a surrogate endpoint or on an effect on a clinical endpoint other than survival or irreversible morbidity as recorded in 21 CFR 601.41 (Subpart E) or 21 CFR 314.510 (Subpart H).

†-- Total approval time was adjusted based on management decision. This is a legacy practice and is no longer exercised.